REMARKS

In the Office Action of February 17, 2004, the Examiner rejected claims 1-8, 12, 14 and 20-21 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,700,253 ("Parker"), and further in view of U.S. Patent 5,462,523 to Samson ("Samson I"). Claims 9-11 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Parker, Samson I and U.S. Patent 6,053,903 ("Samson II"). Applicants respectfully disagree with the Examiner's characterization of the cited references, and request reconsideration and reexamination of the application. With this response, claims 20 and 21 have been canceled. Claims 1-12, 14 and 19 remain pending.

Claim 1 of the present invention is directed to a medical device. In particular, the medical device comprises a tube having a coil in a stressed, radially expanded condition; a braid extending over at least part of the coil; and a polymeric layer positioned over and contacting at least the coil. The polymeric layer maintains the coil in its stressed radially expanded condition.

As acknowledged by the Examiner in the Office Action, Parker does not teach a braid extending over a coil. The Examiner cited Samson I as a secondary reference for teaching a medical device with a braid extending over a coil. As stated by the Examiner in the Office Action, it would have been obvious to combine Parker with Samson I because, according to Samson, the braid will provide extra support for the coil and allows for better maneuverability of the catheter tip.

In the device of the cited Parker patent, a coil is compression fitted over an inner layer, and an outer layer is applied over the coil. The Parker device does not include a braid, and includes no suggestion for using a braid. The Parker patent is directed to a flexible, kink-resistant sheath. Flexibility at the distal end is often a key feature of an introducer sheath. This is particularly true when the sheath is to be used to access tortuous passageways. For a sheath to be able to bend in those passageways without kinking, the sheath material on the outer part of the bend must be able to stretch, and the corresponding sheath material on the inner part of the bend must compress. The use of a coil reinforcement can elongate or increase (e.g. stretch) the distance between the turns on the outside of the bend very easily with minimum force, while at the same time causing the distance between the turns on the inside of the coil to decrease (e.g. compress) in distance. The very nature of a braid (overlapping woven fibers or filaments) is such that it resists substantial expansion and compression. Therefore, utilizing a coil reinforcement results in a tube structure that is much

more flexible and kink resistant than when a braided reinforcement is used, other things being equal. In contrast to the beneficial property of kink resistance that is obtained when using a coil-reinforced sheath, the use of a braid reinforcement is known to provide favorable torsional control when compared to a coil. Such control is not a subject of the cited Parker patent. Thus, it is clear that although both braids and coils provide reinforcement to a sheath, the two types of reinforcements are provided to address different issues involved when attempting to pass a sheath through the vasculature.

It is true that some embodiments of the device of Samson I include both a braid and a coil, as stated by the Examiner. However, these features are not combined in Samson I in the manner in which they are combined in the present invention. Furthermore, the purpose of the combination, as well as the problems that the combination is intended to solve, are very different from the present invention. Applicants respectfully submit that when the Samson I reference is properly construed, a skilled artisan would not look to it for a solution to problems involving, e.g., the kink resistance and torqueability of an introducer sheath.

Samson I, titled DRUG DELIVERY SYSTEM, is directed to the field of medical perfusion. More specifically, Samson I teaches new perfuser tips for use with medical devices. The perfuser tips of Samson I are provided to allow for the passage of a controlled flow of an agent from the interior of a medical device to the environment external to the device, such as the interior lumen of a body vessel. As stated in Samson I, a distal segment of the catheter assembly includes a flexible perfusion section that permits a controllable flow of fluid to pass to a selected target site within the vessel. The perfusion tip is constructed in such a way that fluids introduced into the catheter at the proximal end perfuse out of longitudinally-spaced openings that are positioned along the tip section. The tip section includes at least two major components, namely an inner stiffener portion which is relatively porous, and an outer perfuser layer which desirably controls the flow of the fluid through the perfusion openings. The inner stiffener may be a coil, and the outer perfuser layer may be a braided tube. Selected filaments of the braided tube can be removed to enable controlled perfusion therethrough. Col. 3, line 61 to Col. 4, line 4. The combination of the coil and braid thus provides a series of passages through which an agent, such as a liquid, can pass from the interior of the device to the exterior environment.

Applicants respectfully disagree with the Examiner's contention in the Office Action that Samson is properly combinable with Parker. The Examiner has stated that Samson is properly combinable with Parker because "according to Samson the braid will provide extra support for

the coil and allows for better maneuverability of the catheter tip." Applicants respectfully assert that the references are not properly combinable, and still further, that the asserted basis for applying Samson in the first place is faulty. The gist of the Samson teaching is that the *coil* provides support for the perfuser *braid*, not the other way around. See, e.g., Col. 2, lines 34-50. Fig. 7 of Samson does show an alternate embodiment wherein a braided inner stiffener is provided. Although this braided stiffener would undoubtedly provide some support to the device, in this instance the braided stiffener is surrounded by a coil. This arrangement is opposite to that of the present invention. Furthermore, it is difficult to see how such a stiffener such as this would allow *better* maneuverability of a catheter tip, as stated by the Examiner in the Office Action. Rather, it would appear that the presence of such a stiff inner member would impair the maneuverability of the device, most particularly, the flexibility and kink resistance of the distal tip section.

Applicants respectfully submit that motivation to combine these references in the manner in which they were combined in the Office Action is lacking. Not only does the Samson reference fail to actually teach the matters stated by the Examiner in the Office Action as providing such motivation (support for the coil and better maneuverability), but it also appears that combining these references would destroy the functions of the medical devices taught in the references. Samson is directed to a perfusion catheter. Such devices are used to deliver fluids to a point of treatment in a body vessel by passing the fluid through the center of the catheter in forcing the liquid out of the catheter through openings in the distal tip. According to Samson, the perfusion tip is constructed in such a way that fluids introduced into the catheter at the proximal end profuse out of openings in the tip. (Col. 3, lines 61-63.) Samson describes the function of the main coil as "supporting the braid and allowing fluid within to pass to the braid and thence out in the space beyond the braid." (Col. 4, lines 47-49.) Thus, the device taught by Samson requires openings along the length of the device to allow the desired perfusion of liquids.

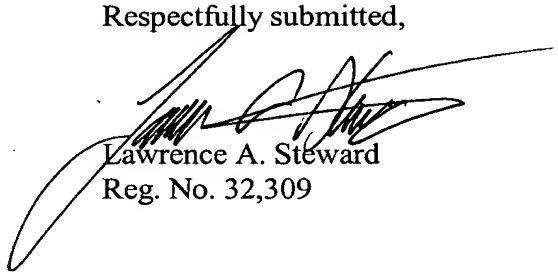
The cited Parker patent discloses a sheath having an outer polymeric layer. Combining the Parker and Samson references would destroy the function of the device taught by Samson. Indeed, the combination of Parker with Samson would render the Samson device inoperable for its intended purpose. Specifically, the outer layer of Parker, when applied to the Samson device, would produce a perfusion catheter with no openings that allow fluids to escape from the catheter. As a result, one of ordinary skill in the art, with no knowledge of the invention claimed

in the present application, would have no technological motivation to combine the Parker and Samson references. Claim 19 has been amended herein to even further illustrate these differences. According to claim 19, as amended, the outer polymeric layer is "substantially imperforate."

With reference to the rejection of claims 9-11 and 19, the Examiner relies on Parker and Samson I for the reasons provided above. Samson II is applied for teaching a polymeric layer of polyurethane or PTFE for a heat shrinking tube with thermally bonded coil. However, the reference does not overcome the deficiencies in the primary and secondary references as described above.

Based on the foregoing, the Applicants respectfully assert that the application is in condition for allowance. Accordingly, it is respectfully requested that a Notice of Allowance be issued. If the Examiner believes that prosecution of this application would be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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